

## REMARKS

Claims 1-3, 5, 10-11, 13-14, 17 and 19 were pending in the application.

Claims 1-3, 5, 10-11, 13-14, 17 and 19 remain pending in the application.

### Claims Rejected under 35 U.S.C. §103

The Examiner has rejected claims 1-3, 5, 10, 11, 13, 14, 17 and 19 under 35 U.S.C. §103 in view of Beale, Lemay et al. and Devita et al.

The Examiner has stated that Beale teaches the use of anti-cortisol compounds in the treatment of patients with AIDS to reduce the catabolic effects associated with AIDS but that Beale does not teach the use of anti-cortisol compounds in a composition with anti-HIV drugs.

The Examiner has stated that Lemay et al. teaches the cortisol blocker ketaconazole in combination with the anti-HIV drug Zidovudine (AZT). Lemay teaches away from the Applicant's invention. Lemay states that the combination of AZT and DHEA **decreased** the ability of AZT to produce the desired effect. (See last line of the abstract). This article would lead those skilled in the art away from the Applicant's invention as in Lemay et al. a combination of an anti-HIV drug and an anti-cortisol drug **lessened** the effect of the anti-HIV drug. There would no reasonable expectation of success, in the present invention, if Lemay is relied upon. Lemay **cannot** be combined with Beale to yield the present invention because of this teaching away.

As to the Devita et al. reference, it simply teaches the combination of anti-HIV drugs. There is nothing taught or suggested in Devita et al. in regards to anti-cortisol compounds. The

discovered link between protease inhibitors and physical symptoms was not discussed or acknowledged in the Devita et al. reference. Devita et al. lends nothing to the Examiner's obviousness rejection. There is nothing taught in this art that was not discussed and pointed to in the Applicant's application. There is no motivation shown that one of skill in the art would combine Beale and Devita et al. to arrive at the present invention.

### **Conclusion**

Because Beale and Lemay et al. cannot be combined due to Lemay et al. teaching away from the present invention and because there is no motivation for one skilled in the art to combine Beale and Devita et al. the Applicant earnestly requests that the §103 rejection be removed. The present application is now in condition for allowance and such action is earnestly requested. A telephone conference regarding this application is earnestly desired and encouraged.

Respectfully submitted,

Dated: 1/22/01

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***Response to Arguments/Declaration***

The following is in response to the arguments/declaration filed 9/25/00:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**35 U.S.C. 112**

The rejection of claims 1-3, 10-11, 13-14, 17 and 19 under 35 U.S.C. 112(1) is withdrawn based on applicant's citation of support for the instant invention as a composition in the instant specification.

**Declaration**

The declaration submitted states that the study supporting the beneficial results was released in May of 2000; however, other than the methodology of the experiment, the actual study or data was not provided to the examiner as factual evidence. To be of probative value, any objective evidence should be supported by actual proof; moreover, the declaration does not outweigh the evidence supporting the prima facie case of obviousness as set forth in the office actions mailed 3/2/00 and 7/21/00. The 35 U.S.C. 103 of record is not solely based upon administration of the compounds singularly, although applicant admits in p.2 of the instant reply that the specification teaches that the compounds may be administered separately or as "...a composition defined as having both components systemically in the human body".

As cited previously, Beale teaches the use of anti-cortisol compounds such as HMB, DHEA, Ipriflavone and phosphatidylserine in the treatment of patients with AIDS to reduce the catabolic effects associated with AIDS (col.2-col.8, line 19). Beale does

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not explicitly teach the use of anti-cortisol compounds in a composition with anti-HIV drugs.

Lemay et al. teach the cortisol blocker ketaconazole in combination with the anti-HIV drug Zidovudine (AZT).

5           Devita et al. teach that combinations of anti-HIV drugs are beneficial in treating HIV infection for several reasons: Two or more drugs may have additive or synergistic interactions that produce better efficacy than with either drug alone, lower doses than those employed in monotherapies- possibly decreasing toxicity, delaying the emergence of a resistant virus that can escape drug inhibition, and targeting of different  
10       cellular and tissue reservoirs of the virus; particularly AZT in combination with ddC, ddI or 3TC as the combination of AZT with these agents present stronger synergy over monotherapies or treatment of AZT resistant isolates (DeVita et al., AIDS, 4th edition, pp. 502-504).

15           The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208  
20       USPQ 871 (CCPA 1981).

          The prior art need not explicitly state each side effect, only provide a motivation to combine the two compounds, in this case, applicant's side effects would be viewed as catabolic effects, and given that Lemay and Devita teach the benefits of combination therapies wherein cortisol blockers are used in the treatment of HIV  
25       to increase the synergistic effects of an anti-HIV drug and cortisol blockers are shown by Beale to reduce the catabolic effects of the disease itself, whether the catabolic effects are associated with the use of the anti-HIV drug or the disease

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itself, one of skill would include cortisol blockers in the treatment regime to reduce or alleviate these catabolic effects as an adjunct to a combination therapy.

A *prima facie* case of obviousness is supported when the prior art alone would have appeared to suggest doing, at the time the invention was made, what the applicant has done. It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made that a cortisol blocker could be used in a composition with an anti-HIV drug. One of skill in the art would have been provided with a clear motivation and a reasonable expectation of success to combine the teachings of Beale with that of Lemay and Devita given that any method of treatment would seek to reduce the catabolic effects associated therein, as Lemay and Devita teach the benefits of combination therapies wherein cortisol blockers are used in the treatment of HIV to increase the synergistic effects of an anti-HIV drug and cortisol blockers are shown by Beale to reduce the catabolic effects of the disease itself, whether the catabolic effects are associated with the use of the anti-HIV drug or the disease itself, one of skill would include cortisol blockers in the treatment regime to reduce or alleviate these catabolic effects as an adjunct to a combination therapy.

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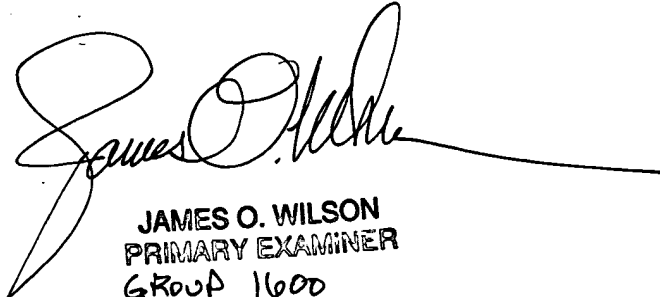
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James Wilson can be reached on (703) 308-1701. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



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